

DOCKET NO: C01037.70003.US

ADEMARK OFFICE

CHARTER TOO,

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):

Robert L. Bratzler et al.

Serial No.:

09/776,479

Confirmation No.:

7139

Filed:

February 2, 2001

For:

IMMUNOSTIMULATORY NUCLEIC ACIDS FOR THE

TREATMENT OF ASTHMA AND ALLERGY

Examiner:

Q. Nguyen

Art Unit:

1636

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, Washington, D.C. 20231, on the **E** day of July, 2003.

Collen Bellevan.

Colleen Sullivan

Commissioner for Patents Washington, D.C. 20231

SUPPLEMENTAL STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing of a first Office Action on the merits.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

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The Applicant hereby makes the following additional information of record in the above-identified application.

The following co-pending applications that may contain subject matter related to this application are enclosed unless the earlier application is identified herein and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application:

Docket Number	Serial Number	Filing Date	Inventor(s)
C01037.70016.US	09/009,634	1/20/98	Hutcherson et al.
C01037.70021.US	09/949,194	9/7/01	Peterson et al.
C01037.70025.US	10/017,995	12/14/01	Bratzler
C01039.70053.US	09/931,583	8/16/01	Krieg et al.
C01039.70057.US	09/965,101	9/26/01	Davis et al.
C01039.70058.US	10/023,909	12/18/01	Davis et al.
C01039.70060.US	10/112,653	3/29/02	Krieg et al.
C01039.70061.US	10/161,229	6/3/02	Krieg et al.
C01039.70062.US	10/187,489	7/2/02	Krieg et al.
C01039.70063.US	10/224,523	8/19/02	Krieg et al.
C01039.70065.US	10/272,502	10/15/02	Krieg et al.
C01039.70067.US	10/300,247	11/20/02	Davis et al.
C01039.70068.US	10/306,522	11/27/02	Krieg et al.
C01039.70069.US	10/314,578	12/9/02	Krieg et al.
C01039.70070.US	10/382,822	3/6/03	Krieg et al.
C01040.70006.US	09/316,199	5/21/99	McCluskie et al.
C01040.70010.US	09/768,012	1/22/01	Davis et al.
C01041.70016.US	09/954,987	9/17/01	Bauer et al.
C01041.70019.US	10/140,013	5/6/02	Schetter et al.
C01041.70029.US	10/212,133	8/1/02	Lipford et al.
C01041.70031.US	10/265,072	10/5/02	Lipford
C01041.70035.US	10/373,381	2/24/03	Wagner et al.
C01041.70037.US	10/407,952	4/4/03	Wagner et al.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

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1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;

- 2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
- 3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

Robert L. Bratzler et al., Applicants

Maria A. Trevisan, Reg. No.: 48,207

Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2211

Telephone: (617) 720-3500

Docket No. C01037.70013.US

Date: July 5, 2003

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APPLICATION NO.: 09/776,479 ATTY. DOCKET NO.: C01037-0013.US FORM PTO-1449/A and B (Modified) CONFIRMATION NO.: 7139

al.

EXAMINER: Q. Nguyen Vich ON DISCLOSURE FILING DATE: February 2, 2001 STATEMEN BY APPLICANT APPLICANT: Robert L. Bratzler et al. JUL 1 7 2003 GROUP ART UNIT: 1636

U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited	Date of Publication or of Rule	
		Number	Kind Code	Document	of Cited Document MM-DD-YYYY	
	A20	5,922,766		Acosta et al.	07-13-1999	
	A21	6,174,872	B1	Carson et al.	01-16-2001	
	A22	6,339,068	B1	Davis, et al.	01-15-2002	
	A23	6,406,705	B1	Davis, et al.	06-18-2002	
	A24	6,429,199	B1	Krieg et al.	08-06-2002	

FOREIGN PATENT DOCUMENTS

Diaminio 3	Cite No.	Foreign Patent Document		nent	Name of Patentee or Applicant of Cited	Date of Publication of	Translation
		Office/ Country	Number	Kind Code	Document (not necessary)	Cited Document MM-DD-YYYY	(Y/N)
	B36	wo	99/11275	A2	The Regents of the University of California	03-11-1999	
	B37	WO	99/52549	A1	SmithKline Beecham Biologicals S.A.	10-21-1999	
	B38	wo	00/20039	A1	The Regents of the University of California	04-13-2000	
	B39	wo	00/62787	A1	The Regents of the University of California	10-26-2000	

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Cite		Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item	
Initials No		(book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s),	
		publisher, city and/or country where published.	*
	C165	ARKWRIGHT, P. et al., "Intradermal administration of a killed Mycobacterium vaccae suspension (SRL 172) is	
		associated with improvement in atopic dermatitis in children with moderate-to-severe disease", J. Allergy Clin.	
		<i>Immunol.</i> , March, 2001, pp. 531-534	
	C166	HARTMANN, G. et al., "CpG DNA: A potent signal for growth, activation, and maturation of human dendritic	
		cells", Proc. Natl. Acad. Sci., August, 1999, vol. 96, pp. 9305-9310	
	C167	HARTMANN, G. et al., "CpG DNA and LPS induce distinct patterns of activation in human monocytes", Gene	
	1	Therapy, 1999, vol. 6, pp. 893-903	
	C168	IHO, S. et al., "Oligodeoxynucleotides containing palindrome sequences with internal 5'-CpG-3' act directly on	
		human NK and activated T cells to induce IFN-γ production in vitro", J Immunol., October 1, 1999, vol. 163, no.	:
		7, pp. 3642-3652	′
	C169	JAKOB, T. et al., "Bacterial DNA and CpG-containing oligodeoxynucleotides activate cutaneous dendritic cells	
		and induce IL-12 production: implications for the augmentation of Th 1 Responses", Int. Arch. Allergy	
		<i>Immunol.</i> , 1999, vol. 118, pp. 457-461	
	C170	JAKOB, T. et al., "Activation of cutaneous dendritic cells by CpG-containing oligodeoxynucleotides: a role for	
	1	dendritic cells in the augmentation of Th1 responses by immunostimulatory DNA", <i>J Immunol.</i> , 1998, vol. 161,	
	1	no. 6, pp. 3042-3049	
	C171	KLINMAN, D. et al., "Contribution of CpG motifs to the immunogenicity of DNA vaccines", J Immunol., 1997,	
		vol. 158, no. 8, pp. 3635-3639	
	C172	KLINMAN, D. et al., "Immune recognition of foreign DNA: a cure for bioterrorism?", Immunity, August, 1999,	
		vol. 11, pp. 123-129	
C173	C173	KRANZER K. et al., "CpG-oligodeoxynucleotides enhance T-cell receptor-triggered interferon- γ production	
		and up-regulation of CD69 via induction of antigen-presenting cell-derived interferon type I and interleukin-12"	-
		Immunology, 2000, vol. 99, pp. 170-178	
	C174	KRIEG, A. et al., "Mechanisms and therapeutic applications of immune stimulatory CpG DNA", Pharmacology	
		& Therapeutics, 1999, vol. 84, pp. 113-120	

/N. M. Minnifield/ (05/06/2009)

of

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Serial No.: 09/776,479 JUL 1 7 2003 Conf. No.: 7139 **EXAMINER**

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DATE CONSIDERED

/N. M. Minnifield/ (05/06/2009)

TECH CENTER 1800; #EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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TECH CENTER 1600/2900 DOCKET NO: C01037.70013.US

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/N. M. Minnifield/ (05/06/2009

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 15 day of July, 2003.

Colleen Sullivan

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Transmitted herewith are the following documents:

- Information Disclosure Statement and USPTO Form 1449 [X]
- [X]Related Applications and Cited References
- Return Receipt Postcard [X]

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

No fee is considered due. If a fee is considered due, the fee may be charged to Deposit Account 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

Robert L. Bratzler et al., Applicants

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Docket No. C01037.70013.US

Date: July 15, 2003

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